10. (New) The method according to claim 5, wherein the cationic liposome consists essentially of 2-0-(2-diethylaminoethyl) carbamoyl-1, 3-dioleoylglycerol and a phospholipid.

A3

11. (New) The method according to claim 10, wherein the phospholipid is lecithin.

Remarks

Favorable reconsideration in view of the herewith presented amendments and remarks is respectfully requested.

Election/Restriction Requirement

In accordance with the Examiner's request, applicants affirm the election of the species poly I: C, with traverse. Applicants expressly reserve the right to file a divisional application directed to the non-elected invention.

Priority

Applicants gratefully note the Examiner's acknowledgement for the claim for foreign priority based on an application filed in Japan on March 24, 1998.

Specification

In accordance with the Examiner's request, applicants have reviewed the application and have presented an amended paragraph to page 12 of the specification.

Claim Rejection/35 USC § 112

Claims 1, 2, 3 have been rejected under 35 USC § 112, first paragraph. The Examiner alleges that the claims are not based on an enabling disclosure.

With all due respect, applicants disagree with the Examiner.

Applicants urge that the Examiner has misinterpreted the present invention to be an invention relating to gene therapy. This is not correct. The present invention has nothing to do with gene therapy.

Simply, poly (I): poly (C) is not a gene but a nucleic acid. Thus, the cited documents in connection with gene therapy are not relevant documents against the present invention.

Poly (I): poly (C) is a drug capable of inducing interferon, for example *in vivo*. It is well-known for interferon to be effective in hepatitis and the effective amount is also well-known. In fact, interferon itself is now sold for the treatment of hepatitis.

The present specification shows that the complex of the present invention can clinically induce a sufficient amount of interferon continuously (see Test Example 3). In addition, it shows that interferon is induced chiefly in the liver in particular (see Test Examples 1 and 2). Thus, the present invention is not unpredictable at all as alleged by the Examiner.

For the above reasons, applicants urge reconsideration and withdrawal of the Examiner's §112, first paragraph rejection.

Claim Rejection/35 USC § 103

Claims 1, 2 and 3 have been rejected under 35 USC §103(a) as being unpatentable over U.S. Patent No. 5,298,614 to Yano et al (Yano).

Applicants respectfully traverse this rejection.

The present invention relates to a new method of utilizing a known complex. Prevention of hepatitis is no longer encompassed by the present claims.

The complex used in the method of the present invention can induce interferon in an effective amount with poly (I): poly (C) of much less amount than poly (I): poly (C) alone. If poly (I): poly (C) alone is administered to a mammal, it is very difficult to make interferon induced for the treatment of hepatitis with safe amounts of poly (I): poly (C). The complex can significantly induce interferon in the liver. These effects are unexpected for one skilled in the art if the cited documents are combined.

With all due respect, it is urged the Yano neither teaches nor suggests the instant invention. There is simply no teaching in Yano that would have suggested to the artisan that the complex utilized in the presently claimed method could be employed in the treatment of hepatitis.

Reconsideration and withdrawal of this rejection is respectfully requested.

CONCLUSION

It is believed that all of the present claims are in condition for allowances. Early and favorable action by the Examiner is earnestly solicited.

AUTHORIZATION

If the Examiner believes that issues may be resolved by telephone interview, the Examiner is respectfully urged to telephone the undersigned at (212) 801-2146. The undersigned may also be contacted by e-mail at ecr@gtlaw.com.

No additional fee is believed to be necessary. The Commissioner is hereby authorized to charge any additional fees which may be required for this amendment, or credit any overpayment to Deposit Account No. 50-1561.

In the event that an extension of time is required, or which may be required in addition to that requested in a petition for an extension of time, the Commissioner is requested to grant a petition for that extension of time which is required to make this response timely and is hereby authorized to charge any fee for such an extension of time or credit any overpayment for an extension of time to Deposit Account No. 50-1561.

Dated: October 24, 2002

Respectfully submitted,

By: Eugene C. Rzucidlo

Eugene C. Rzucidlo
Registration No. 31,900
Customer Number: 32361

ATTACHMENT

[It is apparent from Figure 1 that every sample expressed β-interferon mRNA and that β-interferon was induced in a dose-depending m anner. The agent of present invention induced more β-interferon than that poly(I) poly(C) alone did.]

It is apparent from Figure 1 that every sample expressed β-interferon mRNA and that β-interferon was induced in a dose-depending manner. The agent of present invention induced more β-interferon than the poly (I) poly (C) alone did.

[The amount of expressed β-interferon mRNA in mouse tissues Other t han liver was determined in the same manner as Text Example 1. The result is shown in Figure 2.]

The amount of expressed β-interferon mRNA in mouse tissues other than liver was determined in the same manner as Text Example 1. The result is shown in Figure 2.

4. (New) A method of treating hepatitis in a mammal in which interferon is effective, comprising the steps of:

1. intravenously, transmucossally, or hepatic intra-arterially administering to the mammal a complex of a cationic liposome with poly (I): poly (C) which has a mean length within the range of 100 to 500 bp; and
2. inducing chiefly in the liver an effective amount of interferon.

5. (New) A method of inducing interferon chiefly in the liver comprising intravenously, transmucossally, or hepatic intra-arterially administering to a mammal an effective amount for the treatment of hepatitis in the mammal of a complex of a cationic liposome with poly(I): poly (C) which has a mean length within the range of 100 to 500 bp.

6. (New) The method according to claim 4, wherein the hepatitis is hepatitis C.

7. (New) The method according to claim 4, wherein the cationic liposome consists essentially of 2-0-(2-diethylaminoethyl) carbamoyl-1, 3-dioleoylglycerol and a phospholipid.

8. (New) The method according to claim 7, wherein the phospholipid is lecithin.

9. (New) The method according to claim 5, wherein the hepatitis is hepatitis C.

10. (New) The method according to claim 5, wherein the cationic liposome consists essentially of 2-0-(2-diethylaminoethyl) carbamoyl-1, 3-dioleoylglycerol and a phospholipid.

11. (New) The method according to claim 10, wherein the phospholipid is lecithin.